Umbilical Cord Blood Banking System in Virginia

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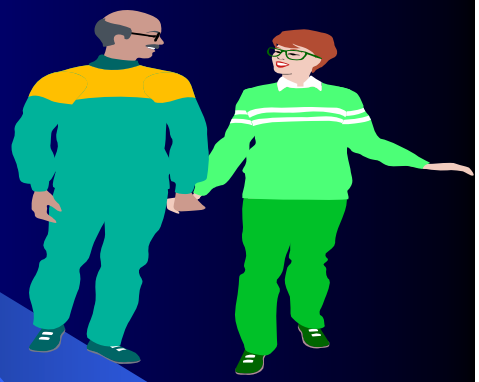
Cord Blood Banking in Virginia

- Are there any other States or countries that have a publicly supported cord blood banking system
- Feasibility and cost of establishing a statewide umbilical cord blood banking system in Virginia

Other States who support cord blood banking

- Florida
- Massachusetts
- New Jersey

Florida's Program



- Establishes the Public Cord Blood Tissue Bank
- Collect, screen for infectious and genetic diseases, tissue typing, cryopreserve, resource to public
- Collaborative consortium: Univ. of Florida, Univ. of So. Fla., Univ. of Miami, and the Mayo Clinic, Jacksonville.
- Any pregnant woman admitted to a hospital or birthing facility may be offered the opportunity to donate umbilical cord blood, but cannot be required to donate cord blood.
- Any provider receiving financial gain from cord blood must provide written disclosure to the postpartum woman or parents
- Consortium may charge reasonable fees to recipients

Massachusetts

- In partnership with the University of Massachusetts Medical School at Worchester
- Establish and maintain a public bank for collecting and storing umbilical cord blood and placental tissue donated by maternity patients at participating hospitals
- All licensed hospitals must inform pregnant women under their care of the opportunity to donate cord blood
- Educate maternity patients about cord blood banking
- Any research institution may reach agreement to provide payment of the estimated expenses of the collection and storage of the donated umbilical cord blood and placental tissue

Massachusetts Biomedical Research Advisory Council

- Establish a Biomedical Research Advisory Council consisting of 15 members
- Must include the Secretary of Health and Human Services and the Commissioner of Public Health
- The Council will make recommendations to the Governor about biomedical research relating to cord blood and placental tissue
- The Council must meet periodically and submit an annual report to the Governor, the president of the Senate, and the speaker of the House

New Jersey

- Coriell Institute for Medical Research established the New Jersey Cord Blood Bank
- Was provided five million dollars in State Funding as a loan, repayment upon release of cord blood for therapy
- Establishes strong relationships between the cord blood bank and the collecting hospitals
- Written informed consent must be signed by each woman who chooses to donate cord blood
- Coriell Institute is an internationally known, not for profit biomedical research institution, with a long history of cell banking, cryogenic storage, and retrieval of human cell cultures

Maryland (regulates but does not support)

- Each hospital must allow a pregnant patient to donate umbilical cord blood to a certified cord blood bank
- The patient cannot be charged for the donation
- Collection not required by employees when it violates bona fide religious practices (doctors, nurses, etc.)
- Hospitals are not required to make arrangements for donations

Other Countries

- **Brazil: Public cord blood bank founded in 2002, collection at maternity hospital in Rio De Janeiro. Donations are typed for HLA-A and included in the Donor Registry Database.**
- **Colombia: In Jan. 2005, established public program for banking cord blood through the University of Antioquia. Cost paid through national health plan. Not legal to export cord blood out of Colombia.**

Other Countries

- **India: Government sponsored program announced in July 2005. Contracted with private firm Histostem to set up cord blood banking in 4 locations around the country.**
- **Korea: Seoul Cord Blood Bank is not a government institution. Private firm Histostem with an inventory of 60,000 units. Government has not set up ethical and legal guidelines for collection of cord blood.**

Other Countries

- **Singapore: Government-supported Singapore Cord Blood Bank, established in 2004. Collections are free but units are released for transplant cost of $26,000. If a child has donated to bank, can get cells free.**
- **Australia: National network of cord blood banks in Melbourne, Sydney, and Brisbane. Can be used by patients inside Australia or outside of the country. Cord blood is registered in the Australian Bone Marrow Registry.**

Other Countries

- **European Union: Forbids making a profit by selling body material, but clinics can charge fees to recover operating expenses.**
- **France: Private cord blood banking is illegal, as cord blood is considered a national resource. Three hospitals collect cord blood with inventory of 3,000 units.**

Other Countries

- UK: National Health Service collects cord blood for the public good. Collected in three hospitals in London. Inventory of 7,000 cord blood samples, 80 units released for transplant.
- Italy: Network of public cord blood banks, maintained by national health system. Private cord blood banking is prohibited.

U.S.: National Marrow Donor Program

- National Marrow Donor Program is part of a world wide network of 500 medical facilities
- Program searches for a donor or cord blood unit when a patient needs a transplant
- It facilitates an average of 200 bone marrow or blood cell transplants each month
- Has over 45,000 cord blood units dispersed in various hospitals
- Cord blood banks in Minnesota, California, Oregon, Colorado, North Carolina, Florida, Illinois, Michigan, New Jersey, Washington State, and Missouri

What is happening now in Virginia?

- Only 5% of umbilical cord blood is now being banked in Virginia by public institutions
- Primarily used by pediatric oncologists for childhood cancers
- Most stored cord blood is being deposited in private storage facilities

First Step in public banking of umbilical cord blood

- Develop a system to register existing cord blood supplies
- Would involve some type of information technology database
- ? Authority to use private cord blood in an emergency

What would be needed to store umbilical cord blood samples

- Would need a capacity to store 40,000 doses minimum
- Would need to store cells for up to five years
- Would need to type cells and sort cells

Cord Blood Storage Options

- Integrate cord blood storage into an existing cell storage infrastructure
- Start new cord blood initiative under State supervision
- Contract with a private sector provider

Integrate into an existing blood storage system

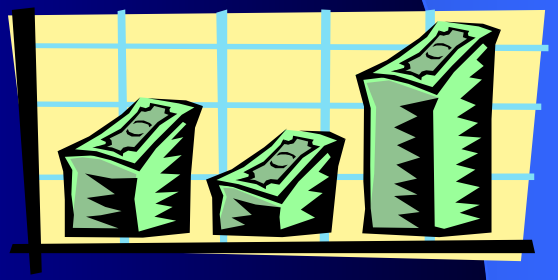
- Probably the least expensive option
- Would involve coordination with existing blood banking facilities VCU-MCV, UVa Hospital, Carilion, Sentara, and Fairfax Inova
- Would supplement the existing system

What would this involve at each site?

- 400 to 500 square feet of space
- 2 Freezers, $10,000 each
- 2 Vent Hoods, $8,000 each
- Access to Fluorescent cell sorting and tissue typing

Costs at each of the five sites

- $200,000 for equipment at each site
- Two lab tech personnel for each site at a price of $50,000 each
- Supplement the salary of an existing supervisor to take on new program

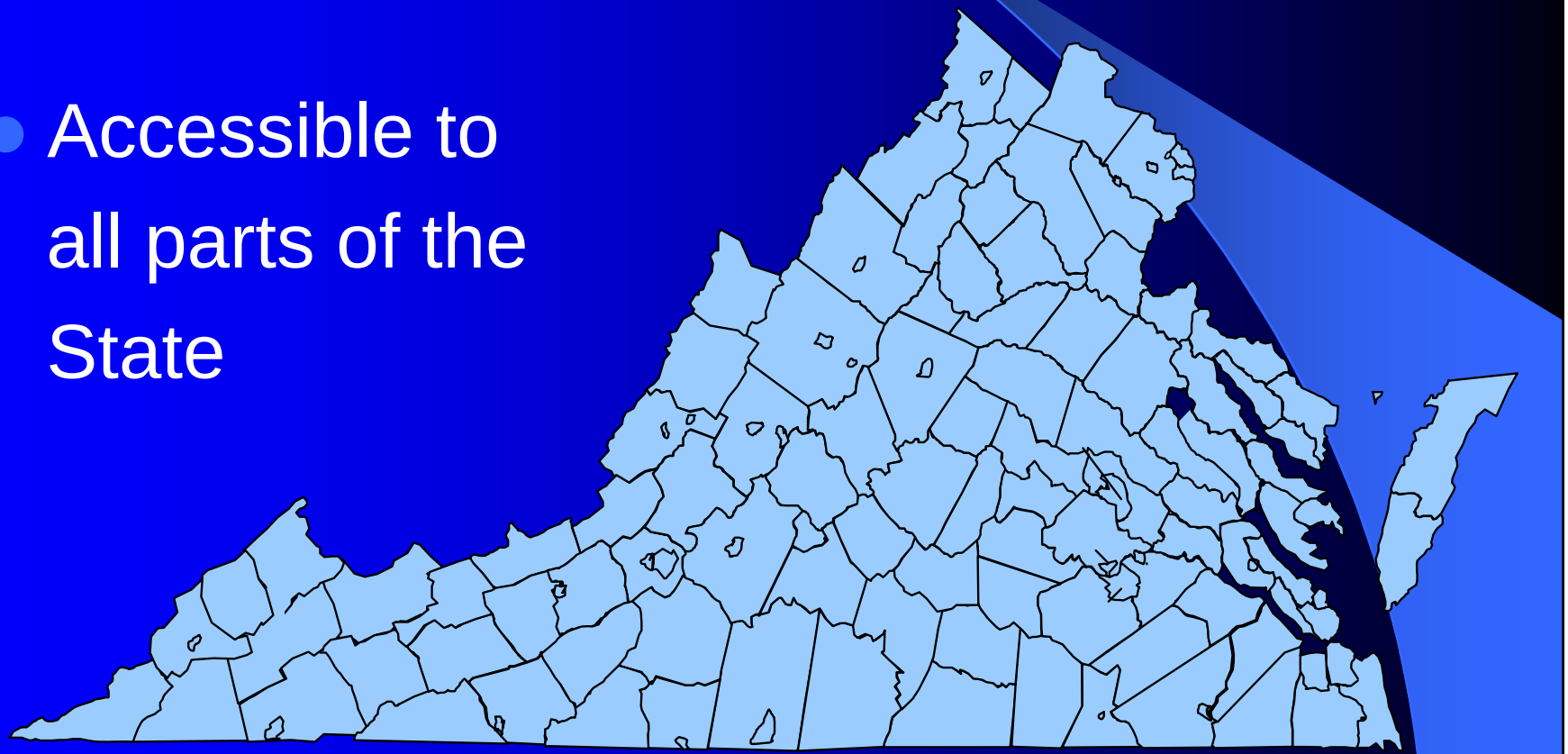


Projected Costs of integrating into blood bank system

- 1.5 to 2 million dollars for start – up year
- Maintenance costs less than one million dollars per year
- Costs of monitoring and regulating system

Geographical Diversity

- Accessible to all parts of the State

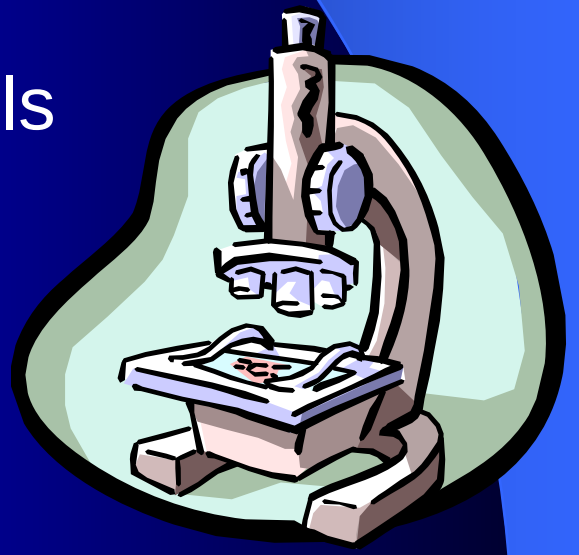


New Initiative – New System

- An alternative to integration into an existing system is to start a new initiative of umbilical cord blood banking
- Would need a new building or a renovated structure built specifically for the intricate, detailed lab work associated with stem cell banking
- Need a Fluorescent Cell Sorter: $250,000

Disadvantages

- Constructing a pure GMP facility, Level 5 Laboratory, with strict regulation
- Could cost as much as 20 million dollars
- FDA would regulate stem cells as a drug

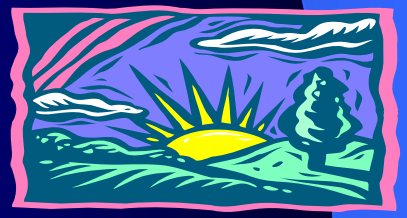


Third option: Contract

- Contract with private stem cell storage companies
- Consider a bid process
- ? Control Issues,
  ? Problems getting
  cord blood in emergencies

Expectations

- HIPAA privacy standards: no patient specific data, cannot trace sample back to patient
- Turnover Goal: No cells are over five years old. As new cells enter the system, older cells exit
- Could sell exiting cells to companies who want to use them for research (Lilly, Merck). Revenue could help offset costs



Questions?????